

## REMARKS

Claims 8-28 are pending in this application. Withdrawn claims 10-13, 15-17, 21-24 and 26-28 are cancelled herewith. Therefore, after entry of this Amendment, claims 8-9, 14, 18-20 and 25 are pending for consideration.

### **I. Rejection under 35 USC § 103**

The Examiner has rejected claims 8-9, 14, 18-20 and 25 under 35 U.S.C. 103(a) stating that the claims are unpatentable over Kuehne *et al.* (CA 1 268 714, 1990) in view of Kern *et al.* (US 5 712 097).

The Examiner states that Kuehne *et al.* teaches a stabilized chlorite solution and its use in cancer treatment (e.g. metastatic solid tumors such as primary or metastatic adenocarcinoma). The Examiner proceeds to acknowledge that the claims differ from Kuehne *et al.* in that they are directed to pancreatic carcinoma. However, the Examiner states that Kern *et al.* teaches that a primary pancreatic carcinoma is adenocarcinoma that is associated with DCC. The Examiner therefore concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute adenocarcinoma with pancreatic carcinoma and that the recitation "the carcinoma characterized in DCC" is inherently possessed.

Further, the Examiner states:

**Because of unpredictability recognized in cancer treatment, one would have motived [sic] to find the specific types that is [sic] classified adenocarcinoma and extend Kuehne's chlorite treatment into pancreatic carcinoma with reasonable expectation of success. (emphasis added)**

On one hand, the Examiner acknowledges the unpredictability in cancer treatment and yet, on the other hand, states that the teachings of Kuehne can be extended with reasonable expectation of success. With respect, this reasoning is not sustainable under 35 U.S.C §103

Applicant submits that there is no teaching or suggestion in either of the cited references to combine the teachings to result in Applicant's claimed subject matter.

It is well established that, in order to sustain a rejection under 35 U.S.C. §103, it is the burden of the USPTO to establish a *prima facie* case of obviousness, In re Reuter, 651 F.2d 751, 210 U.S.P.Q. 249 (CCPA 1981). In asserting such a case of obviousness, the Examiner must propose some modification of a particular reference or a combination thereof with another reference in order to arrive at the claimed invention. In this regard, the teachings of a single prior art reference or a primary prior art reference (which is combined with one or more secondary prior art references) must be sufficient to justify a conclusion that any proposed modification or combination of references is what one of ordinary skill in the art would have found obvious to do at the time the invention was made, In re Linter, 458 F.2d 1013, 173 U.S.P.Q. 560, 562 (CCPA 1972). Moreover, the Courts have held that there must be some logical reason apparent from the evidence of record that would justify a modification or combination of prior art references, In re Regel, 188 U.S.P.Q. 132 (CCPA 1975). If there is no such reason, the *prima facie* case of obviousness has not been made out, Oscar Mayer Foods Corp. v. Sara Lee Corp. 15 U.S.P.Q. (2d) 1204, (D.C.Wis., 1990).

Hindsight combination of references is not a valid basis for rejection under 35 U.S.C. §103, In re Adams, 148 U.S.P.Q. 742 (CCPA 1966) and In re Skoll,

187 U.S.P.Q. 481, 484 (CCPA 1975). Further in Twin Disc Inc. v. United States, 10 Cl. Ct. 713; 231 U.S.P.Q. 417, 425 (Cl. Ct 1986), the Court stated:

**... it is now clear beyond cavil that it is not permissible to ascertain factually what the inventors did and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct the claimed invention.**

Citing Orthopedic Equipment Co., Inc. v. United States, 702 F.2d 1005, 1012; 217 U.S.P.Q. 193, 199 (Fed. Cir. 1983), the Court in Twin Disc further stated that it is incorrect to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.

Applicants submit that the Examiner's suggestion that a motivation would have existed to combine these references "because the assurance and reliance for the drug treatment(given) is critical [sic] to increase successful rate and patient compliance" is improper based on well established case law discussed above. Further, there is no teaching or suggestion in Kuehne *et al.* to use the stabilized chlorite solution in the treatment of pancreatic carcinoma. Further, there is no teaching or suggestion in Kern *et al.* to a treatment for pancreatic carcinoma. Applicant submits that a person skilled in the art would not merely combine two distinct references, one being directed to the use of an aqueous chlorite solution for the treatment of tumors and the other being directed to polynucleotide and polypeptide sequences encoding a novel suppressor gene, in the hopes that a new treatment for pancreatic carcinoma would result.

Applicants therefore submit that there is no motivation in either of the cited references to combine these two references to result in Applicants' claimed subject matter and that the Examiner has failed to establish the *prima TECH/522815.1*

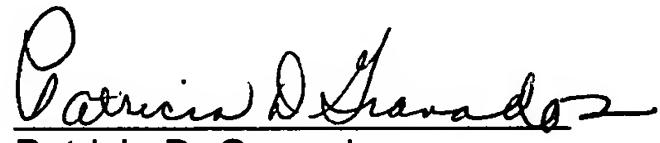
*facie* case of obviousness needed to sustain a rejection under 35 U.S.C. §103(a). Applicants therefore request withdrawal of the rejection under 35 U.S.C. §103(a).

## CONCLUSION

In light of the above amendments and comments, Applicants respectfully request that the current rejection be withdrawn and that a timely Notice of Allowance should be issued in this application. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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